

Having described my invention, I claim:

Sub B<sub>1</sub> → (1) A method of treating a lipidemic disorder with a nicotinic acid formulation suitable for oral administration once-a-day as a single dose without causing drug-induced hepatotoxicity in an individual to a level which would require use of the nicotinic acid formulation to be discontinued by the individual, comprising:

Ins A<sub>1</sub> 5 orally administering to the individual once-a-day as a single dose an effective amount of an intermediate release nicotinic acid formulation without causing drug-induced hepatotoxicity in the individual to a level which would require use of the intermediate nicotinic acid formulation by the individual to be discontinued, the intermediate release nicotinic acid formulation having

Ins A<sub>1</sub> 10 a dissolution curve similarity fit factor  $F_2$  of at least about 79, and

an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket), according to U.S. Pharmacopeia XXII, at about 37°C in deionized water at about 100 rpm, as follows

15 (a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus,

(b) between about 15% and about 30% of the nicotinic acid is released after about 3 hours in the apparatus,

(c) between about 30% and about 45% of the nicotinic acid is released after about 6 hours in the apparatus,

20 (d) between about 40% and about 60% of the nicotinic acid is released after about 9 hours in the apparatus,

(e) between about 50% and about 75% of the nicotinic acid is released after about 12 hours in the apparatus, and

(f) at least about 75% is released after about 20 hours in the apparatus.

(2) A method of claim 1, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(3) A method of claim 1, wherein the nicotinic acid formulation is a tablet.

5 (4) A method of claim 3, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375mg, about 500mg and about 750mg.

(5) A method of claim 1, wherein the *in vitro* dissolution profile is as follows:

10 (a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

15 (d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% is released after about 20 hours in the apparatus.

20 (6) A method of claim 5, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(7) A method of claim 5, wherein the nicotinic acid formulation is a tablet.

(8) A method of claim 7, wherein the tablet contains nicotinic acid in an amount selected from the group consisting of about 375mg, about 500mg and about 750mg.

(9) A method of claim 1, wherein the *in vitro* dissolution profile is as follows:

(a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% is released after about 20 hours in the apparatus.

(10) A method of claim 9, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(11) A method of claim 9, wherein the nicotinic acid formulation is a tablet.

(12) A method of claim 11, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375mg, about 500mg and about 750mg.

(13) A method of claim 1, wherein the single dose is administered to the individual during the evening or at night.

(15) A method of claim 13, wherein the single dose is administered to the individual during the evening or at night between about 8pm and 10pm.

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orally administering to the individual once-a-day as a single dose an effective amount of an intermediate release nicotinic acid formulation without causing drug-induced hepatotoxicity in the individual to a level which would require use of the intermediate nicotinic acid formulation by the individual to be discontinued, the intermediate release nicotinic acid formulation containing at least about 1000 mg of nicotinic acid and having

a dissolution curve similarity fit factor  $F_2$  of at least about 44, and

an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket), according to U.S. Pharmacopeia XXII, at about 37°C in deionized water at about 100 rpm, as follows

- (a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus,
- (b) between about 15% and about 30% of the nicotinic acid is released after about 3 hours in the apparatus,
- (c) between about 30% and about 45% of the nicotinic acid is released after about 6 hours in the apparatus,
- (d) between about 40% and about 60% of the nicotinic acid is released after about 9 hours in the apparatus,
- (e) between about 50% and about 75% of the nicotinic acid is released after about 12 hours in the apparatus, and
- (f) at least about 75% is released after about 20 hours in the apparatus.

(17) A method of claim 16, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(18) A method of claim 16, wherein the nicotinic acid formulation is a tablet.

(19) A method of claim 16, wherein the *in vitro* dissolution profile is as follows:

- (a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;
- (b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% is released after about 20 hours in the apparatus.

(20) A method of claim 19, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(21) A method of claim 19, wherein the nicotinic acid formulation is a tablet.

(22) A method of claim 1, wherein the *in vitro* dissolution profile is as follows:

(a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% is released after about 20 hours in the apparatus.

(23) A method of claim 22 wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

(24) A method of claim 22, wherein the nicotinic acid formulation is a tablet.

5 (25) A method of claim 16, wherein the single dose is administered to the individual during the evening or at night.

(26) A method of claim 25, wherein the single dose is administered to the individual during the evening or at night between about 6pm and 12 am.

(27) A method of claim 25, wherein the single dose is administered to the individual during the evening or at night between about 8pm and 10pm.

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